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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,789	11/08/2000	Samsun Lampotang	UF-246XC1	2465

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[REDACTED] EXAMINER

CROSS, LATOYA I

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1743

DATE MAILED: 01/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/708,780	LAMPOTANG ET AL	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 November 2000.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1.) Certified copies of the priority documents have been received.
 2.) Certified copies of the priority documents have been received in Application No. _____.
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 5</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-3, 9-11, 15, 28, 31, 37 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,282,953 to Ayer et al.

Ayer et al teach a method for monitoring the deliverance of a medication into a patient's body. The method comprises providing a detectable marker in combination with a beneficial agent. The detectable marker is one that can be detected non-invasively, such as those detectable in the patient's breath (col. 5, lines 45-47). As exemplary markers, Ayers et al teach dimethylsulfoxide which emits an odor detectable with a sulfur detector. The beneficial agent is a drug used to treat disease or other pathological conditions (col. 7, line 3-6). The reference teaches that in an implantable delivery system and implanted in the patient. Subsequently, the marker is vaporized a detected in the patient's expelled breath (col. 8, lines 36-39).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102 (e) in view of the teachings of Ayer et al.

*drop in
view of
cancelled
claims*

3. Claims 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,432,362 to Shinar et al.

Shinar et al teach acoustic wave based chemical sensors. The sensors have a substrate

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(82), at least two electrodes (84, 86) connected to the substrate and a coating (88) positioned over the substrate and at least one electrode, as recited in claim 1. The coating is disclosed as small particulate matter. Shinar et al teach the use of fluoropolymers, specifically Teflon. Shinar et al teach that coating absorbs gases such as volatile organic compounds. The device contains an oscillator output (80) that provides a detectable signal in response to the presence of the target analyte. At col. 6, lines 4-12, Shinar et al teach that the concentration of the analyte will also be detected by the frequency of an oscillator output (80).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 103 in view of the teaching of Shinar et al.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 6 and 12-14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al in view of US Patent 5,167,972 to Greenberg et al.

Ayer et al is described above. Ayer et al fail to teach the particular markers recited in claim 6. With respect to claims 12-14, Ayer et al teaches only intravenous delivery of the medication.

Greenberg et al teach that flavorants are conventionally added to drugs as sweeteners and flavor enhancers. Greenberg et al teach that cinnamaldehydes, citrus oils, fruit essences, etc can be added to drugs (col. 5, lines 21-37 and col. 9, lines 24-31). It would have been

obvious to add flavorants to the drugs of Ayer et al because, like the dimethylsulfoxide taught by Ayer et al, most flavorants have a distinctive scent that would be able to be detected in the breath of the patient.

With respect to claims 12-14, Applicants' recited manners for delivering the medicine are known and conventionally used in the art of medications. It would have been obvious to one of ordinary skill in the art to deliver the medication of Ayer et al in any manner that is suitable and easiest to use.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Ayer et al and Greenberg et al.

6. Claims 4, 5, 7, 8, 16, 17, 21-25, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al as taught by Shinar et al, WO 99/12471 to Katzman et al, US Patent 5,771,890 to Tamada and US Patent 5,042,501 to Kenny et al.

Ayer et al is described above. Ayer et al teach detecting a marker by breath analysis, but fails to teach any particular breath analyzing instrument to use.

The analyzers recited by Applicants in claims 4, 5, 7, 8, 29 and 30 are conventionally used in the art to detect substances in gases and/or air. Shinar et al teach using SAW devices to determine analytes in gases. Katzman et al teach using mass spectrometers; Tamada teaches transdermal detection and Kenny et al teach using spectrophotometers. Each of the devices contains means for collecting data and further means for outputting the data to the user.

It would have been obvious to one of ordinary skill in the art to use any known measuring device to detect the markers of Ayer et al. Those recited by Applicants are known

to be suitable in gas analysis and would provide an effective means for determining the presence of markers in breath samples and providing output for the user to determine the results of the analysis.

7. Claims 18-20, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al in view of US Patent 5,776,783 to Kell.

Ayer et al is described above. Ayer et al fail to teach comparing the marker in the patient's breath with a predetermined profile.

Kell is directed to monitoring therapeutic agent consumption by using markers in combination with therapeutic agents. As a part of the monitoring method, Kell teaches measuring the concentration of marker and comparing that with an expected (predetermined) marker as an indication of the consumption of the therapeutic agent.

It would have been obvious to one of ordinary skill in the art to use the comparison method of Kell in monitoring the consumption of the drugs of Ayer et al because the comparison method provides a manner whereby the consumption can be validated to assure that the patient has in fact consumed the drugs.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Ayer et al and Kell.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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January 13, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700